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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,127	05/13/2002	Robert Llewellyn Clancy	BSWV-P01-002	1497

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EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,127	CLANCY ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2005* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *20 and 37-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-39* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2/2/03 + 2/22/05
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II (claims 21-36) in the reply filed on 27 May 2005 is acknowledged. The traversal is on the ground(s) that the inventions share a common technical feature, that the Examiner has not shown a serious burden in considering all the inventions together, and the invention provides a contribution over the prior art. This is not found persuasive because the inventions employ structurally distinct parameters for assessment resulting in different technical features, a showing of serious burden is not required for restriction under the PCT rules (35 USC 121 and 372), and the distinctions recited over the prior art of record are not included in the instant claims. The arguments are addressed in detail below:

A. The inventions employ structurally distinct parameters for assessment resulting in different technical features and the combination of inventive categories does not meet the requirements of 37 CFR 1.475,

Group I, claim(s) 20 and 22-36 method detecting only IgA (1st method).

Group II, claim(s) 21-36 method detecting only IgA1 (2nd method).

Group III, claim(s) 37 method detecting either or a combination of IgA and/or IgA1 (3rd method).

Group IV, claim(s) 38, drawn to a kit (1st product).

Group V, claim(s) 39, method detecting only IgA (4th method).

Further, PCT unity of invention sets forth requirements regarding different categories of inventions and their combination when a "special technical feature" is determined. However the combination of 4 methods and a product is not considered a possible combination. Please see 37 CFR 1.475.

B. The Examiner has not shown a serious burden in considering all the inventions together. This argument was carefully considered but not found persuasive because burden of search is not required under the PCT rules. Also, arguments directed to MPEP 800 are MOOT because the restriction was not considered with respect to US restriction practices.

C. The invention provides a contribution over the prior art. Applicant contends that the invention relates to pre-post mortem measurements of IgA and/or IgA1 levels in the mantle zone or reticular epithelium. This allows for measurement in "live" children and prediction of susceptibility to ALTE/SIDS. However these limitations are not recited in the instant claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

2. Claims 20 and 37-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/27/05. Currently claims 21-36 are under consideration.

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered. See references cited on pages 15-16.

4. The information disclosure statements filed 2/2/03 and filed 2/22/05 have been considered as to the merits before First Action.

Oath/Declaration

5. A new oath or declaration is required because Non-initialed and/or non-dated alterations have been made to the oath or declaration (Inventor Clancy – Post Office Address). See 37 CFR 1.52(c). The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Specification

6. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

7. The use of the trademarks has been noted in this application. (i.e. BECKMAN on page 7). They should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

8. The disclosure is objected to because of the following informalities:

A. Page 2 line 20, the sentence end with two periods ".."

B. Page 9 line 11 refers to Appendix C, however no such appendix is provided.

C. Two Table 1's are listed in the disclosure - one on page 8 and another on page 13.

Appropriate correction is required.

Claim Objections

9. Claims 21 and 28 are objected to because of the following informalities: Claims 21 and 28 utilize acronyms (see ALTE, SIDS, and ELISA). Although the terms may have art-recognized meanings, it is not clear if applicant intends to claim any prior art definition of the abbreviations. The terms should be defined in their first instance. The initial explanation will convey intended meaning of subsequent abbreviations in the claims. Please define.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 23, 30, 34, 35 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 23, *symptoms* of URTI are vague and indefinite. Will the sample be collected after URTI or not? What is a symptom of URTI? It is suggested that the actual symptoms are recited, however Applicant is cautioned not to introduce new matter in to the claims.

B. Claim 30 recites a "rapid-near subject assay" however this is vague and indefinite because it in not clear as to what will meet the limitation of a rapid-near subject assay. For example, any assay conducted at the bedside of the patient. Please clarify.

C. Claim 34 is vague and indefinite in reciting "an internal personal standard" because it is not clear if this is any "personal" standard arbitrarily selected for comparison (test samples compared to normal samples at the same time) or is it Applicants intent to imply that the standard is normalized against the tested subject (the samples from the same subject are compared at different time points). Please clarify.

D. Claims 35 and 36 are vague and indefinite in reciting "other indices" because it is not clear what other materials Applicant intends to encompass. As recited the method measures the ratio of immunoglobulin levels and compares that measurement to *other indices*. In claim 36 the other indices are referred to as "acute phase reactants and other cellular components". This is also indefinite because it is not clear what Applicant considers an "acute phase reactants or other cellular components". The specification and the claims do not define Applicants intended meaning therefore the metes and bound of the claims cannot be determined and one of ordinary skill in the art would not be appraised of the instant invention. It is suggested that the terms are omitted from the claims in order to obviate this rejection.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 21, 22, 24, 25, 26, 27, 28, 33, 34, 35, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Friedman et al. (Clinical and Experimental Immunology, 1996, Vol.103, No.2, pages 206-211).

Friedman et al. teach a method of detecting rotavirus (acute life threatening episodes-ALTEs or sudden infant death syndrome-SIDS) in infants.

Total IgA1 and IgA2 (Applicant's other indices or other cellular components) levels were in serum and saliva samples from infants (claim 22) at birth, at 6 weeks of age, and at 12 weeks of age via quantitative ELISA (claim 28). The detection of IgA1 and IgA2 are disclosed to be possibly significant in mucosal immunization and defense of the respiratory and intestinal tracts. See abstract and page 207 1st column 3rd paragraph. Although the reference is silent with respect to ALTEs and SIDS this is deemed and inherent property because the disorders are taught to include dysregulation of mucosal immunity. The specification teaches that ALTEs and SIDS are involved in mucosal immunity on page 3 lines 1-2.

Both secreted IgA1 and IgA2 measurements and ratios (ration of immunoglobulin levels) were evaluated in normal/control infants (whole unstimulated saliva see tables 1 and 2), in infants who were feed with breast milk or bottle at the time of sampling/subject is not fasting (whole unstimulated saliva see table 3), and after the infants were immunized with a rotavirus vaccine (see table 4). See page 207 2nd column 4th paragraph through page 209.

IgA1 was found to be exclusively produced in infants and was expressed in much higher concentrations at 6 weeks of age when compared to older children and adults (normal population standard). See pages 208 and 209. In this study IgA1 was shown to be expressed early in infant development and useful in detecting retrovirus antibody activity in infants (page 208 2nd column).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

II. Claims 23 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al. (Clinical and Experimental Immunology, 1996, Vol.103, No.2, pages 206-211) in view of Gleeson et al. (Pediatric Research, 1993,Vol.33, No.6, pages 554-556).

Please see Friedman et al. (Clinical and Experimental Immunology, 1996, Vol.103, No.2, pages 206-211) as set forth above.

Friedman et al. differ from the instant invention in not specifically teaching sample collections after an upper respiratory tract infection (URTI) or radial immunodiffusion techniques.

However, Gleeson et al. teach a method of measuring SIDS after URTI in an infant. The mucosal immune response was evaluated in saliva samples collected from the SIDS infant 2 days after birth and during weeks 2, 3, 4, 6, and 8 after birth. The IgA levels were measured by electroimmunodiffusion (radial immunodiffusion). A mild respiratory tract infection was diagnosed in the SIDS infant at 3 ½ weeks of age. See page the results showed that little or no levels of IgA were measured in the saliva for the first 3 weeks of life. However the IgA levels increased in the 4th week (after UTRI infection) and continued to rise through the 8th week. The increased was five times higher than the age-related median for 8 week-old infants. See page 555 3rd paragraph.

It would have been obvious to one of ordinary skill in the art at the time of the invention to employ the method evaluating IgA in radial immunodiffusion assays after URTI as taught by Gleeson et al. to measure IgA1 (the specific IgA) of Friedman et al. because Gleeson et al. taught that IgA levels increased after UTRI infection and the radial immunodiffusion procedure exhibited an increase that was five times higher than the age-related median for 8 week-old infants. See page 555 3rd paragraph.

One of ordinary skill would have been motivated to measure IgA levels at an increased expression (after URTI) because the prior art has shown that IgA expression in infants is low or nonexistent. See Friedman et al. –Discussion page 208-209 and Glesson et al. –Analysis of variability page 536.

III. Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al. (Clinical and Experimental Immunology, 1996, Vol.103, No.2, pages 206-211) in view of Rylatt et al. (WO 97/09620).

Please see Friedman et al. (Clinical and Experimental Immunology, 1996, Vol.103, No.2, pages 206-211) as set forth above.

Friedman et al. (Clinical and Experimental Immunology, 1996, Vol.103, No.2, pages 206-211) fail to particularly teach immunoglobulin detection (IgA1 and IgA2) with a test strip (assay device) allowing for in situ or near subject-assay measurements.

Rylatt et al. disclose a test strip device that can be utilized to measure various analyte including antibodies, which encompass immunoglobulins. See page 5 lines 21-28. The device is useful in biological fluids such as saliva. See page 6 lines 24-26. The device is also taught to be employed at convenient locations including point of care locations (near-subject assays). See page 1 lines 18-23. Further, the test strip assay system is simple and rapid. See page 4 lines 18-21.

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the IgA1 analysis teachings of Friedman et al. into the test strip device of Rylatt et al. because Rylatt et al. taught that test strip devices allowed for assay processing at convenient locations (page 1 lines 18-23) and the test strip assay system is simple and rapid (see page 4 lines 18-21).

13. For reasons aforementioned, no claims are allowed.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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